Policy on Enhancing Public Access to Archived Publications Resulting From NIH-Funded Research

Engaging the Public in Medical Research is a Priority

To protect the public trust, we must:
- Manage our scientific portfolio
- Have transparent management practices
- Encourage scientific communication with the public

To improve participation in clinical trials, we must reach out to:
- community-based physicians
- a diverse public

House Appropriations Language

Departments of Labor, Health and Human Services, and Education Subcommittee Report, July, 2004

*Access to research results.--*The Committee is very concerned that there is insufficient public access to reports and data resulting from NIH-funded research. This situation, which has been exacerbated by the dramatic rise in scientific journal subscription prices, is contrary to the best interests of the U.S. taxpayers who paid for this research. The Committee is aware of a proposal to make the complete text of articles and supplemental materials generated by NIH-funded research available on PubMed Central (PMC), the digital library maintained by the National Library of Medicine (NLM). The Committee supports this proposal and recommends that NIH develop a policy, to apply from FY 2005 forward, requiring that a complete electronic copy of any manuscript reporting work supported by NIH grants or contracts be provided to PMC upon acceptance of the manuscript for publication in any scientific journal listed in the NLM's PubMed directory. Under this proposal, NLM would commence making these reports, together with supplemental materials, freely and continuously available six months after publication, or immediately in cases in which some or all of the publication costs are paid with NIH grant funds. For this purpose, 'publication costs' would include fees charged by a publisher, such as color and page charges, or fees for digital distribution. NIH is instructed to submit a report to the Committee by December 1, 2004 about how it intends to implement this policy, including how it will ensure the reservation of rights by the NIH grantee, if required, to permit placement of the article in PMC and to allow appropriate public uses of this literature.

NIH Public Access Policy

Congress - Appropriations Language

Consolidated Appropriations Act, 2005. November 20, 2004
Joint Explanatory Statement – Page 1147

The conferees are aware of the draft NIH policy on increasing public access to NIH-funded research. Under this policy, NIH would request investigators to voluntarily submit electronically the final, peer reviewed author's copy of their scientific manuscripts; six months after the publisher's date of publication, NIH would make this copy publicly available through PubMed Central. The policy is intended to help ensure the permanent preservation of NIH-funded research and make it more readily accessible to scientists, physicians, and the public. The conferees note that the comment period for the draft policy ended November 16th; NIH is directed to give full and fair consideration to all comments before publishing its final policy. The conferees request NIH to provide the estimated costs of implementing this policy each year in its annual Justification of Estimates to the House and Senate Appropriations Committees. In addition, the conferees direct NIH to continue to work with the publishers of scientific journals to maintain the integrity of the peer review system.

NIH Public Access Policy

NIH Must Lead the Way in Public Access

NIH-supported research is essential to improving human health and public access to publications resulting from this research is vital.

- **Good for Science**
- **Good for NIH**
- **Good for the Public**

Why Public Access?

- **ARCHIVE.** Keep a central archive of NIH-funded research publications—for now and in the future, preserving vital medical research results and information for years to come.

- **ADVANCE SCIENCE.** Create an information resource that will make it easier for scientists to mine medical research publications, and for NIH to manage better its entire research investment.

- **ACCESS.** Provide electronic access to NIH-funded research publications for patients, families, health professionals, scientists, teachers, and students.

NIH Public Access Policy Embraces Growing Trend

NIH examined the access policies of the top 20 journals based on citation impact for medicine and medical research and of the top 50 journals published by members of FASEB.

As of October 2004:

- 80% of the 20 high impact journals allow public access of some sort through HighWire press within 12 months of publication.

- 78% of the 50 FASEB journals offer public access within 12 months.

Proposed Public Access Policy

In September 2004, NIH proposed a policy to enhance public access to archived publications resulting from NIH-funded research.

- The draft policy requested, but did not require, that NIH-supported investigators submit electronically to the NIH the final, peer-reviewed author's copy of manuscripts upon acceptance for publication.

- The manuscripts would be archived in PubMed Central (PMC).

- The author's copy would be made available freely to the public through PMC six months after the publisher's date of final publication (or sooner if the publisher agrees).

Public Comments on Proposed Public Access Policy

We sought input and have been listening to our constituents.

- Public meetings
  - Publishers and Associations (July 2004)
  - Investigators (August 2004)
  - Disease advocacy groups (August 2004)
- Notice in *NIH Guide for Grants and Contracts*
  - September 3, 2004
- Notice in *Federal Register*
  - September 17, 2004
- 6,249 comments received
- Talks, visits, interviews, letters, e-mails

Examples of Comments -- Pros

- Public should have access to research results in a timely manner.

- Enhanced access to information strengthens and expands impact of research.

- Policy provides equal access to less wealthy individuals, institutions, and countries.

- Online access to information is less expensive and easier to obtain.

- Public's concern that access not be driven by business models of publishers.

- Without policy, government favors publishers at publics' expense.

- This policy will improve the visibility of an author's research.

Examples of Comments -- Cons

- Policy will harm financial stability of publishers.

- Policy will adversely impact peer review of research prior to publication.

- Overall implementation of this plan is too costly.

- This policy may lead to an increase in cost for publications or an increase in costs for researchers to submit work.

- The proposed policy does not adequately address copyright issues.

- Policy will financially hurt learned societies and the efforts that they support.

- Regardless of enhanced access, general public does not understand research.

Public Access Policy Revisions

In response to feedback, NIH revised the proposed policy in February 2005 to:

- Emphasize the voluntary nature of authors' submissions.

- Clarify "NIH-funded investigators" to mean those supported with "direct costs" from NIH.

- Provide authors with flexibility to specify the timing of the posting of their final manuscript for public availability through PMC.

- Strongly encourage posting for public accessibility through PMC as soon as possible and within 12 months of the publisher's official date of final publication.

Public Access Policy Revisions

The revisions respond to comments by:

- Addressing "one size fits all" issue by developing a policy that allows maximum flexibility to encourage maximum participation. Now, the **authors** specify the time of posting for public accessibility, as soon as possible and within 12 months of publisher's official date of final publication.

- Recognizing and clarifying that "publication date" is publisher's official date of final publication.

NIH Public Access Policy: Key Provisions

Proposed Policy *September 2004*	*Final Policy* *February 2005*
The draft policy requests, but does not require, that NIH-supported investigators submit electronically to the NIH the final, peer-reviewed author's copy of their manuscripts upon acceptance for publication.	Unchanged
The manuscripts will be archived in PubMed Central (PMC).	Unchanged
The author's copy will be made available freely to the public through PMC six months after the study's publication.	At the time of submission, the author will specify the timing of the posting of his or her final manuscript for public accessibility through PMC. Posting for public accessibility through PMC is strongly encouraged as soon as possible and within twelve months of the publisher's official date of final publication.

14

The Public Access Policy

With input from stakeholders and the public, NIH's *Policy on Enhancing Public Access to Archived Publications Resulting From NIH-Funded Research* has several key elements:

- The Policy strongly encourages, but does not require, all NIH-funded investigators to make the peer-reviewed, author's final manuscript available to other researchers and the public at the NIH National Library of Medicine's (NLM) PubMed Central (PMC) immediately after the final date of publication in a journal.

- At the time of submission, the author will specify the timing of the posting of his or her final manuscript for public accessibility as soon as possible and within twelve months of the publisher's official date of final publication.

Note: The author's final manuscript is the final version accepted for journal publication and includes all modifications from the publishing peer review process.

What to Submit for the Public Access Policy

- The Policy applies to peer-reviewed, original research publications that have been supported in whole or in part with direct costs from NIH. It does not apply to book chapters, editorials, reviews, or conference proceedings.

- The Policy applies to all research grant and career development award mechanisms, cooperative agreements, contracts, Institutional and Individual Ruth L. Kirschstein National Research Service Awards, as well as NIH intramural research studies.

- NIH is requesting that authors submit manuscripts resulting from:

  1) currently funded NIH research projects or

  2) previously-supported NIH research projects if they are accepted for publication on or after May 2, 2005.

- Publications resulting from non-NIH-supported research projects should <u>not</u> be submitted.

Where and How to Submit an Author's Final Manuscript

- Submissions can be made at: http://nihms.nih.gov/

- NIH began accepting submissions on May 2, 2005.

- Since individuals with various roles can be involved in the manuscript submission process, there are numerous scenarios for depositing manuscripts at PMC. The following is an example of how an extramural scientist could submit their manuscript:

  1. An author's designee (e.g., assistant, library, publisher) uploads the manuscript and supporting materials.

  2. At the time of upload, the NIH manuscript submission (NIHMS) system will collect basic information including the journal title, PI name and contact information, and associated NIH award number(s).

  3. An Adobe PDF "receipt" will be generated so the designee uploading the files can verify that all content has been received.

Where and How to Submit an Author's Final Manuscript*

4. The PI is sent an e-mail that the manuscript has been uploaded.

5. The PI follows the link in the e-mail to the PMC site.

6. The PI must then log in to the NIH eRA Commons (if PIs do not have a Commons account, instructions are given on how to quickly establish an account).

7. The PI verifies the manuscript and completes a submission statement that includes setting the timing of posting for public accessibility.

Note: Authors and/or their institutions should ensure that their PMC submissions are consistent with any other agreements, including copyright assignments that they may have, or enter into, with publishers or other third parties.

* See *Authors' Manual* for a full description of the submission process.

NIH Public Access Policy

Timing of Public Accessibility: Immediately to Twelve Months

- The Policy requests and strongly encourages that authors specify posting of their final manuscripts for public accessibility immediately after the final date of journal publication. Authors are given the option to release their manuscripts at a later time, up to 12 months after the official date of final publication.

- NIH expects that only in limited cases will authors deem it necessary to select the longest delay period.

NIH's Public Access Policy Does Not Affect Copyright

- The NIH Policy explicitly recognizes and upholds the principles of copyright.

- Authors and journals can continue to assert copyright in scientific publications resulting from NIH-funding, in accordance with current practice.

- While individual copyright arrangements can take many forms, NIH encourages investigators to sign agreements that specifically allow the manuscript to be deposited with NIH for public posting on PubMed Central. An example of the kind of language that an author or institution might add to a copyright agreement includes the following:

  "Journal acknowledges that Author retains the right to provide a copy of the final manuscript to NIH upon acceptance for Journal publication or thereafter, for public archiving in PubMed Central as soon as possible after publication by Journal."

The NIH Public Access Policy Does Not Alter the Quality of Peer Review

- NIH does not anticipate that its policy will harm or otherwise affect the peer review process for scientific papers.

- Only peer-reviewed manuscripts accepted for publication will be posted in PubMed Central.

- NIH recognizes peer review is a hallmark of quality for journals and is vital for validating the accuracy and interpretation of research results.

- NIH also recognizes that publication in peer-reviewed journals is a major factor in determining the professional standing of scientists.

Will NIH's Public Access Policy Impact Scientific Publishing?

- NIH is not aware that there will be a substantial impact. For example, only a minor portion of articles published in scientific journals result from research funded by the NIH.

  - NIH-funded research represents about 10% of the articles in the nearly 5,000 journals indexed by PubMed.

  - NIH-funded articles account for more than half of the total published articles for only 1% of these journals.

- An increasing number of journals already provide access to the published article immediately or within one year of the publication.

- In addition, the NIH Public Access Policy does not affect authors' freedom to choose the vehicle or venue for publishing their results.

The Policy May Streamline Procedures for Investigators and Institutions

- Effective August 1, 2005, submissions under this Policy afford NIH-supported investigators an alternate means by which they can fulfill the existing requirement to provide publications as part of progress reports.

- It is anticipated that, in the future, investigators applying for new and competing renewal support from the NIH will also utilize this resource by providing links in their applications to their PubMed Central-archived information.

- NIH anticipates that this may reduce, rather than increase, burden for investigators who choose to use this method as part of their application/progress report/close-out submissions.

Benefits to Principal Investigators and Authors

- Principal investigators, and institutions, can use the manuscript submission as an alternative means to fulfill the existing requirement to provide publications as part of progress reports. Note: *Other aspects of annual Progress Reporting requirement cannot be completed through the manuscript submission system – those must be submitted through the normal process.*

- Submission heightens the visibility of the research and enhances the likelihood of early and increased citation.

- Ensures that the manuscript is accessible through PMC, a comprehensive, integrated, biomedical information technology system, so authors will benefit from the tools already available in PMC (e.g., GenBank, Clinical Trials, etc.).

24

Benefits for Archiving in PubMed Central

- When provided by the publisher, PMC provides the journal's published article, a link to the journal article, and/or links to any corrections associated with the article on the publisher's site.

- Offers NIH staff, scientists, and the public the ability to search, view, print, or save (subject to applicable copyright law) Public Access Policy manuscript submissions, full text Journal articles for 178 journals*, as well as citations and abstracts from over 5,000 journals.

- Provides integration with the NIH eRA Commons.

- Integrates manuscripts into the PMC system which includes various resources and tools including: PubMed, GenBank, Genome Map Viewer, Molecular Database, MedlinePlus, Clinical Trials, Taxonomy, Small Molecules (PubChem), and DNA, Protein Sequences, and Protein Structures.

* As of May, 2005

Next Steps

- The NIH National Library of Medicine's Board of Regents has established a Working Group composed of stakeholders to advise the Board on implementation and evaluation of the policy (for the membership roster see http://www.nlm.nih.gov/od/bor/workgroup_roster.html).

- Outreach to funded investigators, institutions, and other stakeholders.

Public Access Policy Resources

- **Public Access Policy Website:**
  http://www.nih.gov/about/publicaccess/

- **NIH Manuscript Submission (NIHMS) System:**
  http://www.nihms.nih.gov/

- **Public Access Policy (NIH Guide for Grants and Contracts):**
  http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html

- **Authors' Manual:**
  http://www.nih.gov/about/publicaccess/publicaccess_Manual.pdf

- **Manuscript submissions can be found on PubMed Central**
  http://www.pubmedcentral.gov

- **Questions and Answers:**
  http://www.nih.gov/about/publicaccess/publicaccess_QandA.htm

- **Public Access Policy Mailbox**
  PublicAccess@nih.gov